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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	DAVI139.001A	2287

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
LY, CHEYNE D	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,229	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 14, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-55* is/are pending in the application.

4a) Of the above claim(s) *15-29, 31-35, 47-52, and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 36-46, 53, and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29 and 31-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traversal of Group I, claims 1-14, 36-47, 53, and 54, in Paper No. 6, filed January 14, 2003, is acknowledged.

2. Claim 47 is withdrawn from examination because it is directed to a method for determining the presence of a disease condition or disorder, which is not of the elected group. Further, claims 15-29, 31-35, 48-52, and 55 are withdrawn from examination because they are directed to a non-elected group.

3. Claims 1-14, 36-46, 53, and 54 are examined on the merits.

Objections

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (Pages 3 and 50, Lines 17 and 26, respectively). Applicant(s) is/are required to delete the embedded hyperlink and/or other form of browser-executable code, or inactivate the hyperlink. See MPEP § 608.01.

5. The disclosure is objected to because of the following informalities: Claim 4 is objected to due to containing inconsistently subscripted vs. superscripted symbols. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 5, 8-13, and 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Specific to claim 4 and 8, the claims recite an assay device comprises the formula of claim 4 or 8, respectively. Claims 4 and 8 are vague and indefinite due to the embodiment of an assay device comprising a formula. It is unclear how an assay device can "comprise" a formula. Claims 9 and 10 are rejected due to being dependent from claim 8.

9. Claim 5, lines 1-2, recites the limitation "the disease condition or disorder is cancer". There is insufficient antecedent basis for this limitation in the claim.

10. Specific to claim 8, line 12, the phrase "from 0 to 1—" causes the claim to be vague and indefinite. Does "from 0 to 1—" represent a range of 0-1 or a range of 0 to 1 plus some unspecified value. Clarification of the metes and bounds is required. Claims 9 and 10 are rejected due to being dependent from claim 8.

11. Claim 11, lines 1-2, recites the limitation "the disease condition or disorder is non-neoplastic". There is insufficient antecedent basis for this limitation in the claim. Claims 12, 13, and 43-46 are rejected due to being directly or indirectly dependent from claim 11.

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-7, 14, 36-42, 53, and 54 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Mendoza et al. (October 1999).

13. Mendoza et al. discloses a device wherein "each well contains four identical 36-element arrays comprising 8 different antigens and a marker protein...Using this new process, arrayed antigens were individually and collectively detected using standard ELISA techniques...applications of this new high-throughput screening (HTS) format include direct cellular protein expression profiling, multiplexed assays for detection of infectious agents and

cancer diagnostics" (Page 778, Abstract). "In a standard ELISA, specificity between antigen and antibody is governed by high affinity associations between an epitope on the antigen and its cognate binding site on the Fab portion of an IgG" (Page 778, column 2, lines 27-32), as in claims 1, 5-7, and 37. Mendoza demonstrates the feasibility of simultaneously and specifically detecting numerous antigens such as the library of antigens listed in Figure 4 using a 96-well, microarray-based ELISA (Page 778, column 2, lines 38-41; and page 784), as in claims 2, 4, 39, 40-42, 53, and 54. Array antigens consist of purified IgGs from various sources such as human or goat (Page 780, Table 1), as in claims 3 and 36. "These markers sites generate very large signal compared to the signal generated from the 1:300 000 dilution of biotin-labeled secondary antibody for its specific cognate antigen on the array" (Page 788, column 1, lines 48-52), as in claim 14. "In this ELISA, the original rabbit IgG monoclonal antibody stock concentration was 4.1 mg/ml. This corresponds to an assay sensitivity of 13.4 ng/ml or 340 *p*g of rabbit IgG monoclonal antibody per well (25-ul total volume)" (Page 788, column 1, lines 26-29), as in claim 38. "[I]t is likely that antibody-based microarray will be used to directly detect proteins expression products from crude cell lysates" (Page 788, lines 40-43), as in claim 7.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-7, 11-14, 36-42, 53, 44-46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza et al. (October 1999) taken with Gallo et al. (US005968513A).

17. Mendoza et al. discloses the limitations of claims 1-7, 14, 36-42, 53, and 54, as cited above. However, Mendoza et al. does not disclose the limitations of claims 11-13 and 44-46 which are the disease is non-neoplastic, disorder of the immune system or an autoimmune disease, and the infectious agents that cause the respective disorders. Gallo et al. discloses pathogens which cause infections which may be treated with recombinant stem cells according to this embodiment of the invention include but are not limited to lymphotropic viruses such as HIV, gram-negative bacilli such as Brucella or Listeria; the mycobacterium which cause tuberculosis or which cause Hansen's disease (leprosy); parasites such as Plasmodium (the etiological agents of malaria), or Leishmania; and fungi (such as those that cause pneumonia and other lethal infections secondary to immunodeficiencies)" (Column 13, lines 43-52), as in claims 11-13 and 44-46.

18. Clearly, a skilled artisan would have been motivated to partake the concept emphasized by Mendoza et al. which is to applying this new high-throughput screening (HTS) format include

direct cellular protein expression profiling, multiplexed assays for detection of infectious agents and cancer diagnostics, for using the new HTS form assay for the detection of flyphotropic viruses such as HIV, plasmodium (the etiological agents of malaria), or Leishmania; and Fungi as taught by Gallo et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the new HTS assay device Mendoza et al. to detect for infectious agents such as lyphotropic viruses such as HIV, plasmodium (the etiological agents of malaria), or Leishmania; and Fungi which cause non-neoplastic diseases or disorder of the immune system as taught by Gallo et al.

CONCLUSION

19. NO CLAIM IS ALLOWED.

20. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

23. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
3/25/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER